

**REMARKS**

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

- I. Claims 1-17 and 19 are rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory matter.
  
- II. Claims 9-17 And 19 Are Rejected Under 35 U.S.C. § 102(b).
  - A. Claims 9-17 and 19 are allegedly anticipated by Suffin *et al.* I- "Neurometric Subgroups In Attentional And Affective Disorders And Their Association With Pharmacotherapeutic Outcome" *J. Clinical Electroencephalography* 26:76-83 (1995).
  
  - B. Claims 9-17 and 19 are allegedly anticipated by Suffin *et al.* II- "Neurometric EEG Classifiers And Medication Response In DSM Disorders". *Annual Meeting American Psychiatric Association Washington D.C., Published: June 1, 1996.*
  
  - C. Claims 9-17 and 19 are allegedly in public use or on sale based upon Suffin *et al.* I, Suffin *et al.* II and Suffin *et al.* III- "Neurometric EEG Predicts Pharmacotherapeutic Outcome In Depressed Outpatients: A Prospective Trial." *Abstract Only, American Psychiatric Association 1997 Annual Meeting, San Diego, CA, May, pg 170.*
  
- III. Claim 18 Is Rejected Under 35 U.S.C. § 103(b)
  - A. Claim 18 is allegedly unpatentable over Suffin *et al.* I in view of United States Patent No. 5,730,146 To Itil *et al.*

B. Claim 18 is allegedly unpatentable over Suffin *et al.* II in view of United States Patent No. 5,730,146 To Itil *et al.*

**I. Claims 1-17 And 19 Are Directed To Statutory Subject Matter**

The Examiner puts forth a two pronged test in order to support a 35 U.S.C. § 101 rejection:

The basis of this rejection is set for in a two-prong test of:

- (1) whether the invention is within the technological arts; and
- (2) whether the invention produces a useful, concrete, and tangible result.

*Office Action*, pg. 2. The Applicants request the Examiner to provide some legal authority for this test. The Applicants point out that the MPEP does not reflect the Examiner's basis:

As interpreted by the Federal courts, 35 U.S.C. 101 has two purposes. First, 35 U.S.C. 101 defines which categories of inventions are eligible for patent protection. ... a machine, an article of manufacture, a composition, or a process ... Second, 35 U.S.C. 101 serves to ensure that patents are granted on only those inventions that are "useful."

*MPEP § 2107.01*, General Principles Governing Utility Rejections. The Examiner has already admitted that Claim 1-17 and 19 are useful:

... claims 1-17 and 19 recite the useful, concrete, and tangible result of predicting the likelihood of response of a patient to a medication ...

*Office Action* pg 2-3. The pending claims are method claims (*i.e.*, process claims) and are statutory according to 35 U.S.C. 101 (*infra*). The Applicants submit that the Examiner has no support for the following conclusion:

... these claims do not apply, involve, use, or advance the technological arts, and therefore deemed to be non-statutory.

*Office Action*, pg. 3. 35 U.S.C. § 101 makes no mention of the technological arts:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101 [emphasis added].

Because the pending claims are useful method (*i.e.*, process) claims, the Applicants respectfully request the Examiner to withdraw this rejection.

## **II. The Claims Are Not Anticipated**

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with the Suffin *et al.* references (*i.e.*, I - III).

The Examiner states that Claims 9-17 and 19 are anticipated by Suffin *et al.* I - III. The Applicants disagree and point out that the Examiner merely states a conclusion and provides no evidence to support the assertion. "It is settled law that the initial burden is on the PTO to present a *prima facie* showing of unpatentability and that, in the absence of such a showing, the claims are to be allowed." *In re Gordon*, 221 USPQ2d 1125, 1127 (Fed. Cir. 1984). The Applicants, therefore, submit that the Examiner has not made a *prima facie* case of anticipation and are not required to rebut the rejection.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have canceled Claims 9 - 19 and added new claims 20 - 54. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. The Examiner will realize that the specification (throughout) provides support for the added claims.

The Applicants respectfully request the Examiner to withdraw the rejection.

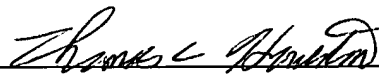
## **III. Claim 18 Is Not Obvious**

The Examiner asserts that Claim 18 is unpatentable over Suffin *et al.* I or II in view of United States Patent No. 5,730,146 To Itil *et al.* The Applicants disagree. However, since Claim 18 was canceled above (without prejudice), this rejection is now moot.

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

Dated: November 2, 2004



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